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Dated: November 19, 2010
Electronic Signature for: Brian C. Trinque, Ph.D.: / Brian C. Trinque, Ph.D./

Docket No.: EISN-018US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Roch Boivin *et al.*

Application No.: 10/507,067
Patent No.: 7,799,827

Confirmation No.: 8892

Filed: November 10, 2004
Issued: September 21, 2010

Art Unit: 1626

For: MACROCYCLIC COMPOUNDS USEFUL AS
PHARMACEUTICALS

Examiner: S. Young

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Dear Sir or Madam:

This statement is respectfully submitted in support of the “Request for Reconsideration of Patent Term Adjustment Under 37 CFR §1.705(d)” for the above-referenced patent. In view of the following, it is respectfully requested that Patentees be granted a minimum patent term adjustment of 1231 days.

In the instant case, the Patent Term Adjustment listed in the Letter Regarding Patent Term Adjustment mailed by the U.S. Patent and Trademark Office on August 18, 2010, is 122 days, representing only A-delay. In the Letter, the Office takes the position that 118 days of Applicant delay would be accorded, and 51 days of Office delay would be removed (page 3).

The Office’s Patent Term Adjustment calculation (“PTA sheet”) (submitted herewith as Appendix A) shows 169 days of manual adjustment, which is the sum of the aforementioned 118 and 51 days. The PTA sheet also lists an additional 51 days of Office delay, and 102 days of Applicant delay (both August 17, 2010). While the placement of these numbers may be erroneous, they effectively remove the 51 days of Office delay as discussed in Applicant’s Petition of July 15, 2010, and in the Office’s

aforementioned letter. (As discussed below, it is Patentees' position that these 51 days should not be considered as "overlapping" days under 37 CFR §1.703(f).) The PTA sheet further lists 118 days of Applicant delay (August 17, 2010), which, presumably, reflects the additional 118 days of Applicant delay discussed in both the Office's and Applicant's letters. Notwithstanding, Patentees agree with the net 122 day A-delay calculation as recited in the Office's Letter.

The PTA sheet indicates 991 days of B-delay. Patentees respectfully submit that this number is not correct for the following reasons. Patentees are entitled to a period of Patent Term Adjustment for failure of the Office to comply with 35 U.S.C. §154(b) and 37 CFR §1.702(b) ("B-delay"). Pursuant to 37 CFR §1.703(b), Patentees are entitled to a Patent Term Adjustment that is equivalent to the sum of the "number of days, if any, in the period beginning on the day after the date that is three years after the date on which the...national stage commenced under 35 U.S.C. 371(b)...and ending on the date a patent was issued." Thus, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of B-delay beginning on the day after the date that is three years from the date on which the above-referenced patent was filed (*i.e.*, September 9, 2007), and ending on the date that the patent issues (*i.e.*, September 21, 2010). This period of delay is 1109 days. Patentees note that a Notice of Appeal was filed on December 18, 2009, but that an Appeal Brief was not filed. Accordingly, Patentees believe that no exclusion of delay was incurred under 37 CFR §1.703(b)(4).

As set forth in 37 CFR §1.703(f), the period of adjustment based on the grounds set forth in 37 CFR §1.702 is the sum of all periods of Examination Delay (A-delay) and the maximum period of Three Years Delay (B-delay), to the extent these periods of delay are not overlapping. Patentees note that the Court of Appeals for the Federal Circuit has clarified that under 35 U.S.C. §154(b)(2)(A), the only way a period of Examination Delay and a period of Three Year Delay can overlap is if they occur on the same calendar day or days. See Wyeth and Elan Pharma Int'l Ltd. v. Kappos, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). It is Patentees' position that there are no overlapping days of A-delay and B-delay in this application. In reference to the calculations of the PTA sheet, Patentees surmise that the 51 days of Office delay and the 102 days of Applicant delay, both entered on August 17, 2010, are an attempt to correct the erroneous 51 days of Office delay entered on April 15, 2010, as discussed in the aforementioned letters of the Office and Applicants. Patentees assert that neither 51 day entry constitutes an overlap under 37 CFR §1.703(f) because the April 15, 2010 entry is erroneous. As such, the indication on the PTA sheet of 51 overlapping days is incorrect. In accordance with 37 CFR §1.705(d), Patentees' position regarding the erroneous entry of overlapping days does not constitute

an issue that was raised, or could have been raised, in an application for patent term adjustment under 37 CFR §1.705(b).

In accordance with 37 CFR §1.705(b)(2)(iii), Applicants submit that the present application is not subject to a terminal disclaimer.

Accordingly, Patentees are entitled to Patent Term Adjustment of 122 days A-delay and 1109 days B-delay, totaling 1231 days.

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that the issued patent reflect a Patent Term Adjustment of **1231 days**.

Dated: November 19, 2010

Respectfully submitted,

Electronic signature: /Brian C. Trinque, Ph.D./
Brian C. Trinque, Ph.D.
Registration No.: 56,593
NELSON MULLINS RILEY & SCARBOROUGH,
LLP
One Post Office Square
Boston, Massachusetts 02109-2127
(617) 227-7400
(617) 742-4214 (Fax)
Attorney/Agent For Applicant